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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,728	03/16/2001	Mahendra S. Rao	UT-0030	7449

7590

06/27/2002

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/736,728

Applicant(s)

Rao et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-49 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

*Gary L. Kunz*  
**GARY L. KUNZ**  
SUPERVISORY PATENT EXAMINER  
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**DETAILED ACTION**

***Election/Restriction***

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6 & 12, drawn to populations of mammalian CNS glial restricted precursor cells, classified in Class 435, subclass 325.
  - II. Claims 7-11, drawn to a method of isolating mammalian CNS glial-restricted precursor cells using antibodies to capture these cells, classified in Class 435, subclass 395.
  - III. Claims 13-19 & 49, drawn to a method of obtaining glial under differentiating conditions, classified in Class 435, subclass 373.
  - IV. Claims 20-36 & 43-47, drawn to a method of treating neurodegenerative disease, or promoting CNS neuronal survival or axonal regeneration, comprising administering glial restricted precursor cells, classified in Class 424, subclass 93.1.
  - V. Claims 37-38, drawn to a method of treating neurodegenerative disease comprising administering genetically modified glial restricted precursor cells, classified in Class 424, subclass 93.21.
  - VI. Claims 39-42, drawn to a method of reducing glial scar formation or promoting wound healing comprising administering glial restricted precursor cells, classified in Class 424, subclass 93.1.

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VII. Claim 48, drawn to a method of screening compounds for neurological activity using glial restricted precursor cells, classified in Class 435, subclass 7.21.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups II-VII are directed to methods for isolating mammalian CNS glial restricted precursor cells involving isolating glial-restricted precursor cells using antibodies (Group II), isolating glial cells under differentiating conditions (Group III), treating neurodegenerative disease comprising administering glial restricted precursor cells (Group IV), treating neurodegenerative disease comprising administering genetically modified glial restricted precursor cells (Group V), reducing glial scar formation/promoting wound healing (Group VI), and a method of screening compounds for neurological activity using glial restricted precursor cells. Each of these methods require physically and functionally distinct elements. For example, the method of Group II requires use of glial-specific antibodies, as well as appropriate support structures to isolate glial cells from neuronal cells, unlike the methods of Groups III-VII, and vice versa. The methods of Groups II-III require the isolation of glial cells, unlike the methods of Groups IV-VI, which require patients with specific disease conditions, which are not required in

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the methods of Groups II-III or VII, and vice versa. The methods of Groups IV-V require patients with neurodegenerative disease states, unlike the method of Group VI, which requires wound healing not required in the methods of Groups IV-V, and vice versa. Moreover, the method of Group V requires genetically modified glial cells, unlike the methods of Group IV, or the methods of Groups II-III & VI-VII, and vice versa. Lastly, the diagnostic method of Group VII requires compounds to be screened and assay conditions that are not required in the methods of Groups II-VI, and vice versa. These inventions are, therefore, patentably distinct, since one is not required for the other.

Groups I and II-IV, VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the CNS glial restricted precursor cells of Group I can be used in other materially different methods, or can be isolated using different methods than those of Groups II-III. The methods of treating patients with neurological conditions, or screening for neurological activity can, alternatively, use isolated protein molecules, neural stem cells, or neuronal precursor cells, none of which are required in the Group I product invention. Therefore, these groups are distinct and separable for the reasons stated.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the lack of coextensive-

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ness of the search and examination for each distinct group would constitute an undue burden on the examiner to search and consider all the separable groups, restriction for examination purposes as indicated is proper.


3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Robert C. Hayes, Ph.D.  
June 26, 2002

  
GARY L. KUNZ  
SUPERVISORY PATENT EXAMINER  
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